



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0012]

Kidney Health Initiative (R18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research/Office of Medical Policy's Kidney Health Initiative Program. FDA, Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP) is announcing its intent to accept and consider a single source application for the award of a grant to the American Society of Nephrology (ASN) to support the Kidney Health Initiative (KHI).

DATES: The application due date is June 30, 2014, by 11:59 p.m., EST.

ADDRESSES: Submit electronic applications to: <http://www.grants.gov>. For more information, see section III of the SUPPLEMENTARY INFORMATION section of this notice.

FOR FURTHER INFORMATION CONTACT: Mark Lauda,

Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak, Bldg. 51, rm. 2212, Silver Spring, MD 20993, 301-796-0381, email: [Mark.Lauda@fda.hhs.gov](mailto:Mark.Lauda@fda.hhs.gov); or Lisa Ko, Office of Acquisition & Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD, 240-402-7592, email: [Lisa.Ko@fda.hhs.gov](mailto:Lisa.Ko@fda.hhs.gov).

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.grants.gov>. Search by Funding Opportunity Number: RFA-FD-14-018.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA-FD-14-018

93.103

A. Background

A memorandum of understanding (MOU) between FDA and ASN signed in September 2012 served as the basis for the establishment of KHI. This award will be made to ASN to enable FDA's support of KHI by defraying some of the direct and indirect costs associated with KHI and KHI projects. The ASN is a 501(c)(3) non-profit organization whose mission is to fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients.

KHI is a public-private partnership whose mission is to advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for disease that affect the kidney by creating a collaborative environment in which FDA and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products. KHI membership is broad and includes stakeholders from government, patient advocacy groups and foundations, pharmaceutical and device companies, professional societies, dialysis providers, and research institutions. KHI helps to effect change through the conduct of projects that address barriers to innovation, facilitate critical evidence generation, and/or elucidate safety concerns. KHI projects

may be submitted for consideration by any of its member organizations (including FDA). Candidate projects are developed and refined through Web-based interactions and during stakeholder meetings. Candidate projects that are successfully developed and receive the endorsement of the KHI Board of Directors are conducted on a volunteer basis by work groups largely (but not exclusively) staffed by individuals from KHI member organizations.

The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the evaluation of products that impact kidney health offers significant value to FDA and the public. Since its inception, KHI has undertaken several projects that have advanced the FDA mission, including (but not limited to) projects elucidating endpoints for lupus nephritis trials and also providing guidance for generating pharmacokinetic data for critical drugs often used in the setting of continuous renal replacement therapies.

### B. Research Objectives

The goals of this program are to develop and maintain an administrative and scientific infrastructure to support the creation and execution of a series of projects under the auspices of KHI, to complement the goals of FDA.

The following KHI activities are supported by this grant:

- Maintaining an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort.
- Identifying and/or hiring a sufficient number of qualified personnel to conduct the necessary research and project-management of all related activities, including review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, and subsequent distribution in the public domain.
- Developing plans for the conduct of identified research plans.

- Identifying, securing, and/or building, and effectively leveraging other resources for the conduct of identified projects.
- Upon completion of a given project, generating project results and recommendations and proposing related studies/projects, if needed, to build on the findings of the project and continuing to leverage established resources and personnel.

### C. Eligibility Information

The following organization is eligible to apply: American Society of Nephrology (ASN).

## II. Award Information/Funds Available

### A. Award Amount

This is a multi-year grant. FDA/CDER intends to fund up to \$500,000 in total costs (direct and indirect) in fiscal year (FY) 2014. Awards are contingent upon the availability of funds.

Subject to the availability of Federal funds and successful performance of the FOA's stated goals and objectives, 4 additional years of support may be available. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year and (2) the availability of Federal FY funds.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Year 1: \$500,000

Year 2: \$500,000

Year 3: \$500,000

Year 4: \$500,000

Year 5: \$500,000

### B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

### III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at <http://www.grants.gov>. Search by Funding Opportunity Number: RFA-FD-14-018. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the Federal Register.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at [http://www07.grants.gov/applicants/organization\\_registration.jsp](http://www07.grants.gov/applicants/organization_registration.jsp). Step 6, in detail, can be found at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>. After you have followed these steps, submit electronic applications to: <http://www.grants.gov>.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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